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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of)
Hans Seiter)
Appn. No. : 09/423,619) Art Unit: 3728
Filed : November 15, 1999)
For : INNER SOLE FOR A SHOE)

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Klaus Bös, declare as follows:

1) I am the Director of the Institute for Sports and Sports Science in Karlsruhe, Germany. I received a degree in Mathematics and Sports from the University of Heidelberg, Germany and my Doctorate in the Dimensions of Motor Activity in 1980. I have done post - doctoral work in the field of Diagnosis of Motor Capabilities. From 1985 - 1987, I was a professor at the University of Frankfurt, Germany. In 1985 I was also the head of the Institute for Sports and Sports Science at the University of Regensburg, Germany. From 1995 to 1998 I was again a professor at the University of Frankfurt, Germany, and from 1999 to the present, I am the head of the Institute for Sports and Sports Science at the University of Karlsruhe, Germany

2) I am familiar with the inner sole which forms an embodiment of the invention disclosed in the application noted above, which inner sole has been identified by Dr. Hans Seiter

as the "VenoPed."

3) I am familiar with the clinical studies conducted by Dr. Hans Seiter on both men and women using the VenoPed inner sole to improve venous flow of blood in the human foot.

4) I, along with Dr. Hans Seiter, gave a talk at the World Congress of the International Union of Phlebology regarding the beneficial effects of the VenoPed. A summary of our conclusions is found in the Enclosure attached hereto.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 19.1.2004

Klaus Bös

Klaus Bös

**14. WORLD CONGRESS OF THE UNION INTERNATIONALE DE
PHLEBOLOGIE****INFLUENCE OF SEVERAL FOOT-MUSCLE PUMP SUPPORTING DEVICES ON
THE VENOUS FLOW VELOCITY DURING A SCHEDULED
WALKING PROGRAM**

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Key words: venous flow rate, foot muscle pump, venous
shoe insole, compression stocking, walking

The main principle in the treatment of the chronic venous insufficiency is the augmentation of the venous flow velocity to reduce and/or prevent the well known problems resulting from the hypertonus of the peripheral veins. Walking which stimulates the foot muscle pump is the ideal sports activity for the veins. The sole of the foot consists of a tight and fine mesh-like network of veins which drain into the deep venous system and into the saphena magna and parva. During walking this foot muscle pump is squeezing this sponge-like network of these foot-sole veins and it comes to an acceleration of the venous flow velocity in the leg. We investigated the influence of a new muscle pump supporting device (shoe insole) on the venous flow rate in comparison with medical stockings of different categories(I,II) during a defined walking schedule with normal volunteers (Vena femor.superfic., Duplex technique, Woodway running-board). In the comparison without any supporting agent we found an acceleration of the venous flow velocity with this new developed shoe insole of 25-30%, with a compression stocking (I) of 20% and with a compression stocking (II) of 30%.

We conclude that this new shoe insole is an effective device to increase the venous flow velocity.